UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	Master File No. 01-12257-PBS
	)	Subcategory No. 06-11337-PBS
THIS DOCUMENT RELATES TO: *United States of America ex rel. Ven-a-Care of The Florida Keys, Inc., v. Actavis Mid Atlantic, LLC, et al.*	)	Civil Action No. 08-cv-10852
	)	Judge Patti Saris

MEMORANDUM OF THE UNITED STATES IN SUPPORT OF THE MOTION TO QUASH DEPOSITION SUBPOENA TO THE CENTERS FOR MEDICARE AND MEDICAID SERVICES

The Case Management Order (CMO) in this matter states that "all fact discovery shall be completed by" April 15, 2011. On April 14, 2011, counsel for Sandoz, on behalf of a consolidated group of defendants, posted a Notice of Subpoena of the Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services (DHHS). Appended to the Notice was a Rule 45 subpoena which purported to require CMS to designate agency officials who would appear for deposition on May 6, 2011, to testify about subjects described in approximately three pages of specifications. *See* Attachment One.

The Court should quash the Notice as untimely given that fact discovery closed on April 15, 2011. Even if the Notice were timely, however, service of the subpoena was contrary to DHHS's *Touhy* regulations, (45 C.F.R. §§ 2.1-2.6) and the appended subject matter specifications are unduly burdensome, overly broad, and seek privileged information. The Government conferred with lead counsel for defendants in an effort to resolve this dispute but was unable to reach agreement.

1. The Subpoena is Untimely

The subpoena to CMS was posted on LexisNexis on April 14, one day prior to the close of fact discovery, and purports to require CMS to begin producing witnesses on May 6 – nearly three weeks after fact discovery ended. Courts consistently have held that discovery requests are untimely when they are not served with sufficient time to allow the opposing party to respond before the close of discovery. *See, e.g., In re Kugel Mesh Hernia Repair Patch Litig.*, 2010 WL 1253566, * 1 (D.R.I. 2010) ("Obviously, serving new discovery requests on the eve of the discovery closure date is not the 'completion' of discovery."); *Williams v. Little Rock Mun. Water Works*, 155 F.R.D. 188, 189 (E.D. Ark. 1993) (denying motion to compel where discovery requests "were not propounded in time for the responses to be due before the discovery cutoff").

Defendants have argued that the Court, by implication, should be considered to have extended the deadline for fact discovery. This contention is unsupported by the record in this case. On March 22, 2011, the parties jointly moved to extend fact discovery and other deadlines in CMO No. 32. (Dkt. 124.) The following day, the Court denied that request. (Dkt. 125). On March 28, 2011, the parties filed a motion titled, "Joint Request for a Status Conference at the Court's Earliest Convenience," in which they asked for "a status and scheduling conference to discuss the issues" raised in the earlier motion for new discovery deadlines. (Dkt. 135) The last sentence in the motion asked for a "provisional extension of the close of fact discovery until such time as [the parties] are able to meet with the Court." On the same day the hearing request was filed, the Court issued a docket entry which, in its entirety, stated:

> ELECTRONIC ORDER entered granting 135 Motion for Hearing. "This case is old. I will hold a status conference in eight weeks to determine what issues are left." Status Conference set for 5/24/2011 at 2:30 P.M.

Defendants construe this Order as allowing them to proceed with entirely new discovery in

this case and to issue Rule 30(b)(6) subpoena specifications to CMS which would require days of testimony, as well as extensive preparation, by agency officials. This construction is untenable in light of the record cited above. First, throughout this MDL, the Court has carefully managed deadlines in all the consolidated cases. As far as the Government is aware, the Court has amended deadlines only by explicit order. Moreover, the Court did not set new dates for the ensuing expert discovery, which began per CMO No. 32 very shortly after the close of fact discovery. From the record as a whole, it appears that, at most, the Court may have been expecting only for the parties to continue ongoing settlement efforts, comply with remaining CMO deadlines, and possibly tie up other unfinished business. Nothing in the record indicates that the Court extended the time for defendants to conduct the considerable and burdensome new fact discovery on which they have now embarked. *Accord* Local Rule 16.1(G) ("The scheduling order . . . can be modified only by order of the judge . . . ."). Based on CMO No. 32, which is the only record by the Court that expressly and unambiguously addresses the issue, fact discovery closed on April 15, 2011.[1]

2. The Notice by Defendants Did Not Comply with DHHS *Touhy* Regulations

By letter dated April 21, 2011, the Government advised defendants that the Notice of Subpoena which had been posted on LexisNexis was not in accordance with the DHHS *Touhy* regulations, 45 CFR §§ 2.1-2.6.[2] In response, on April 29, 2011, counsel for Sandoz directed a written request for a deposition to the CMS Administrator pursuant to the agency's regulations. *See* Attachment Two. Inexplicably, counsel for Sandoz then advised government trial counsel that

[1] Notably, a March 30, 2011 letter from counsel for Actavis to Maryland Medicaid – as well as other documents appended to a recent Ven-A-Care protective order brief (Dkt. 146) – continue to reference the April 15 discovery cutoff and are consistent with discovery having closed on that date.

[2] *See United States ex rel. Touhy v. Ragen*, 340 U.S. 462, 468 (1951) (upholding the authority of federal agencies to set conditions by regulation for the disclosure of information).

he intended to proceed simultaneously with *both* the Rule 45 subpoena posted on LexisNexis, which called for testimony on May 6, as well as the *Touhy* request sent to the Administrator.

Proceeding in this manner would be both unworkable and legally invalid. The Government notified Sandoz that it needed to make an election as to which procedure it would use – notwithstanding that either one would be both untimely and overly burdensome. For the reasons discussed in the other sections of this brief, an attempt to take deposition discovery pursuant to the *Touhy* regulations would also be improper at this juncture in the case. Withdrawal of the Notice in favor of compliance with the *Touhy* process, however, would at least put the dispute in the correct procedural posture. Defense counsel declined to withdraw the Notice.

Congress has granted authority for the head of an Executive Branch agency to "prescribe regulations for the government of his [or her] department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property." 5 U.S.C. § 301. *See generally Cabral v. United States Dept. of Justice*, 587 F.3d 13, 22 (1st Cir. 2009); *Commonwealth of Puerto Rico v. United States*, 490 F.3d 50, 61-62 (1st Cir. 2007). Pursuant to this authority, DHHS issued regulations governing the deposition of agency employees in response to subpoenas and other court demands. *See* 45 C.F.R. §§ 2.1-2.6. In declined *qui tam* cases such as these in which the United States is not a party, the agency's regulations place the initial burden upon the party requesting testimony to provide a written description of "the nature of the requested testimony, why the information sought is unavailable by any other means, and the reasons why the testimony would be in the interest of the DHHS or the federal government." *See* 45 C.F.R. § 2.4.

Compliance with the regulations is necessary because, first, it is a legal prerequisite to the agency's consideration of the request for testimony and, second, the agency's response to the

written request becomes the focus of any judicial review of the matter. *Cabral,* 587 F.3d at 22-23 ("To obtain information from a federal agency, a party must file a request pursuant to the agency's regulations, and may seek judicial review only under the APA.") (quoting *Puerto Rico v. United States,* 490 F.3d 50, 61 (1st Cir. 2007). "Under the APA, a reviewing court may overturn an agency's decision to deny disclosure only if the decision is found to be ''arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.'' *Cabral,* 587 F.3d at 22-23 (quoting 5 U.S.C. § 706(2)(A)).

There is no legal authority for counsel's insistence that defendants may continue on two tracks with respect to the CMS deposition. The law plainly specifies the manner in which defendants should have proceeded from the outset. As with the Notice posted on LexisNexis, the April 29, 2011, letter to the Administrator was also improper given the close of fact discovery. Accordingly, if the Court holds that defendants were legally required to comply with 45 C.F.R. § 2.4, the Government asks that the Court also find that the *Touhy* request is untimely under the discovery deadline set in CMO No. 32.

3. The Subpoena is Unduly Burdensome and Seeks Irrelevant and Privileged Information

A. Undue Burden

The subpoena to CMS is unduly burdensome in light of the extensive efforts by the Government to make witnesses available while litigating with the three defendants against which the Government intervened. There is no dispute that the Judicial Panel's transfer of the False Claims Act cases to the AWP-MDL was for the purpose of efficient and consolidated discovery – for the benefit and convenience of *all concerned.* To that end, the Government allowed deposition questioning by counsel for any party in the AWP-MDL, including those drug companies which had not been sued by the United States. For example, one DHHS employee was questioned by ten

different lawyers over the course of four deposition days.

Although the Government litigated certain discovery issues with Abbott, Dey and Roxane (mostly relating to privilege), there were no complaints by any other MDL litigant concerning the level of access allowed by the Government to agency witnesses over the multiple years that discovery was open in the Government's cases. Notably, the two CMS officials most knowledgeable about the subjects specified in defendants' latest subpoena were collectively deposed for at least eight days. Attorneys for Sandoz, who are now lead counsel on the CMS subpoena, attended at least 39 depositions of present or former DHHS personnel. Although Sandoz lawyers generally passed on their repeated opportunities to question government witnesses, other MDL defendants often took advantage of the opportunity to question agency officials.

In summary, while the Government's intervened cases were pending, defendants had ample opportunity to question CMS officials with knowledge of the subject matter covered in the specifications now before the Court - or on any other subject for that matter. In light of the abundant deposition access that has already been allowed, it is unreasonable to subject CMS, at this late date, to the burdens attendant to the selection, preparation and deposition of officials who can testify about the list of subjects appended to the new CMS subpoena.

B. Over Breadth and Irrelevance

The specifications appended to the subpoena are over broad and lack a discernable legitimate purpose. Specification One is a case in point. It states as an "area of inquiry:"

> The drug pricing information (including without limitation AMPs) provided by Defendants in connection with their pharmaceutical products under Medicaid, including without limitation any analysis, evaluation, review of, or reliance on any representations regarding drug pricing provided [by] the Defendants.

Given the specification's reference to AMPs (Average Manufacturer Prices) and the Medicaid program, this specification appears to relate to information submitted by drug companies in

connection with the Medicaid Rebate Program. As such, in the context of the products manufactured and distributed by defendants at bar, the AMPs would pertain to thousands of NDCs (National Drug Codes).

Putting aside the burdensomeness of the specification, each of the defendants presumably already knows what pricing information it provided to CMS in connection with the Medicaid Rebate Program. To the extent there is any issue about how CMS is permitted to use confidential AMP information, it would be resolved by reference to the Rebate Statute, federal regulations, or the Rebate Agreement which drug companies execute with CMS. (There has also already been considerable deposition testimony on this subject by CMS officials.) Moreover, AMP information received by the Rebate Program is irrelevant to the AWP claims pled by Ven-A-Care. *See In re Pharm. Indus. Average Wholesale Price Lit.*, 582 F.3d 156, 189 (in which the First Circuit was dismissive of AstraZeneca's argument that "it had disclosed accurate pricing data by 'reporting an accurate average manufacturer's price ('AMP'), a close proxy for [the providers' actual acquisition costs], to CMS for purposes of Medicaid'').

As for Specification Two which pertains to "CMS's and the federal Government's policies and decisions to encourage the dispensing of Generic Drugs under Medicaid," any question on this subject should be resolved by reference to official agency pronouncements. *United States v. Lachman*, 387 F.3d 42, 54 (1st Cir. 2004) (holding interpretive issues relating to a government policy is resolved through reference to the official public record).

In light of I) the abundant information already in the public domain, ii) CMS's use of notice and comment rulemaking procedures to develop and announce polices, and iii) the extensive record in the AWP-MDL which consists of the Court's orders and memoranda and the Court of Appeal's review of key holdings, specifications which focus on CMS policies with respect to the use of

AMPs and the dispensing of generic drugs are both burdensome and pointless.

C. Deliberative Process Privilege

Specification Three concerns CMS's consideration and decision on "all proposed or actual amendments to state Medicaid plans." Again, there has already been considerable testimony generally on this topic by CMS officials. With respect to CMS's "consideration" of proposed amendments to State Plans for Medicaid Assistance, the agency's deliberations on whether to approve an amendment are subject to the deliberative process privilege. Accordingly, there is no point in the agency designating a witness who would be constrained by privilege from addressing a principle area of inquiry in this specification.

Finally, Specification Three also sets out an extensive list of proposed State Plan amendments by States, which span more than a decade. The burden associated with providing responsive testimony is patent from the face of the specifications. A more appropriate alternate source for non-privileged information about these amendments are the States which proposed them.

4. Conclusion

One has to question whether defendants truly need the information covered by the specifications given how long they waited to issue this subpoena. As the Court well knows, the AWP-MDL has been pending for almost a decade. The United States was an active party in litigation starting in 2006 and made dozens of high-level agency witnesses available at deposition, including witnesses who testified regarding AMPs and CMS approval of state plan amendments. Discovery in these declined cases has been ongoing for over a year, and yet only at the eleventh hour do the defendants decide they must have additional testimony from CMS.

Based on the foregoing, the United States respectfully requests that the Court quash the subpoena to CMS and additionally that the Court declare that discovery has closed with respect to the deposition requested in defendants' April 29, 2011 letter to the CMS Administrator.

Respectfully Submitted,

For the United States of America,

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May 5, 2011

CERTIFICATE OF SERVICE

I hereby certify that I have this day caused an electronic copy of the UNITED STATES' MOTION TO QUASH DEPOSITION NOTICE TO CMS AND SUPPORTING MEMORANDUM to be served on all counsel of record via electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to LexisNexis File & Serve for posting and notification to all parties.

Date: May 5, 2011

/s/ Justin Draycott
Justin Draycott